PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	Docket No: Q94512
Patrice RICHARD	
Appln. No.: 10/577,132	Group Art Unit: 3761
Confirmation No.: 8183	Examiner: Susan Shan SU

Filed: August 28, 2006

For: PLACENTAL-BLOOD EXTRACTION DEVICE

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The statutory fee of $270.00 is being remitted. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE
23373
CUSTOMER NUMBER

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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I. REAL PARTY IN INTEREST

The real party in interest is PRAXCELL, by virtue of an assignment executed by Patrice Richard (Appellant, hereafter), on April 25, 2006, and recorded by the Assignment Branch of the U.S. Patent and Trademark Office on August 29, 2006 (at Reel 018272, Frame 0051).

II. RELATED APPEALS AND INTERFERENCES

To the knowledge and belief of Appellant, the Assignee, and the undersigned, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be affected by the Board's decision in the instant Appeal.

III. STATUS OF CLAIMS

Claims 1-10, 12, 13, 15-17 and 19 stand rejected and are the subject of this appeal.

Claims 11, 14 and 18 were canceled in an Amendment filed December 1, 2009.

IV. STATUS OF AMENDMENTS

An Amendment was filed, subsequent to the final rejection, on December 1, 2009. The Advisory Action, mailed December 9, 2009, stated that the amendment would be entered for the purposes of appeal.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The instant application is directed toward a placental-blood extraction device and method of extracting placental blood.

According to claim 1, there is required:

at least one extraction needle[1] for piercing the vein of the umbilical cord or of the placenta, a collection vessel[2] connected to said at least one needle via at least one tube[3], and suction means[4] connected to said at least one needle for sucking the placental blood so as to feed said collection vessel;

wherein said suction means comprises a vacuum bottle that simultaneously forms a collection vessel.[5]

According to claim 3, the device according to claim 1 includes at least one injection or extraction site between said at least one extraction needle and said collection vessel.[6]

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[1] See e.g., Specification, page 2, lines 33-35 and FIG. 1, element 10.

[2] See e.g., Specification, page 3, lines 2-4 and FIG. 1, element 20.

[3] See e.g., Specification, page 3, lines 4-5 and FIG. 1, element 40.

[4] Suction means" is to be given "means plus function" treatment under 35 U.S.C. § 112, sixth paragraph. The recited function is suction. The structure corresponding is disclosed as element 30, shown in FIG. 1, and disclosed at, e.g., Specification, page 3, lines 6-29.

[5] See e.g., Specification, page 3, lines 16-23.

[6] See e.g., Specification, page 3, lines 30-33 and FIG. 1, elements 51-53.

According to claim 4, the at least one injection or extraction site recited in claim 3 is provided on the tube.[7]

According to claim 13, there is required:

an extraction needle[8] for piercing the vein of an umbilical cord or of a placenta,

a collection vessel[9] in fluid connection with the needle via a tube[10], and

a vacuum[11] in fluid connection with the needle so as to feed said collection vessel;

wherein the vessel creates the vacuum.[12]

According to claim 17, there is required:

providing an extraction device comprising an extraction needle[13], a collection vessel[14] in fluid connection with the needle via a tube[15], and a vacuum[16] in fluid connection with the needle so as to feed said collection vessel; and

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[7] See e.g., Specification, page 4, lines 6-8.

[8] See e.g., Specification, page 2, lines 33-35 and FIG. 1, element 10.

[9] See e.g., Specification, page 3, lines 2-4 and FIG. 1, element 20.

[10] See e.g., Specification, page 3, lines 4-5 and FIG. 1, element 40.

[11] See e.g., Specification, page 3, lines 16-29.

[12] See e.g., Specification, page 3, lines 18-21.

piercing the vein of the umbilical cord or of a placenta and drawing out fluid with the aid of the vacuum;[17]

wherein the collection vessel is of the Redon type.[18]

Although the above summary refers to specific portion of the specification and drawings in describing where the claim elements find support in the application and where the underlying structure for means plus function language can be found, it should be noted that these references are intended to be illustrative in nature and should not be considered to be limiting in nature.

[13] See e.g., Specification, page 2, lines 33-35 and FIG. 1, element 10.

[14] See e.g., Specification, page 3, lines 2-4 and FIG. 1, element 20.

[15] See e.g., Specification, page 3, lines 4-5 and FIG. 1, element 40.

[16] See e.g., Specification, page 3, lines 16-29.

[17] See e.g., Specification, page 2, line 33-page 3, line 15.

[18] See e.g., Specification, page 3, lines 16-23.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3-7, 9, and 17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deverre (US Patent 7,131,958) in view of Dracker (US Patent 5,356,373).

Claims 2, 11, 12, 18, and 19 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Deverre in view of Dracker as applied to claim 1 above, and further in view of Seddon et al. (US Patent 6,024,731).

Claims 13-16 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Dracker in view of Seddon.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deverre and Dracker as applied to claim 7 above, and further in view of Darling, Jr. (US Patent 6,213,986).

Claim 10 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deverre and Dracker as applied to claim 1 above, and further in view of Van Der Heiden et al. (US Patent 5,879,318).

In the Amendment filed December 1, 2009, claim 1 was amended to incorporate the subject matter of claim 11. This Amendment was entered by the Examiner in the Advisory Action dated December 9, 2009. Accordingly, the rejection of claim 11 is now applicable to claim 1.

VII. ARGUMENT

I. CLAIMS 1, 2-7, 9, 11, 12 AND 17-19 STAND REJECTED UNDER 35 U.S.C. § 103(a) AS ALLEGEDLY BEING UNPATENTABLE OVER DEVERRE (US PATENT 7,131,958) IN VIEW OF DRACKER (US PATENT 5,356,373), AND FURTHER IN VIEW OF SEDDON ET AL. (US PATENT 6,024,731).[19]

The Examiner must allow the claims unless "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[20] Appellants respectfully submit that this criteria for establishing obviousness has not been met with regard to the instant application.

Claim 1 recites, *inter alia*:

> A placental-blood extraction device comprising at least one extraction needle for piercing the vein of the umbilical cord or of the placenta, a collection vessel connected to said at least one needle via at least one tube, and suction means connected to said at least one needle for sucking the placental blood so as to feed said collection vessel;
>
> wherein said suction means comprises a vacuum bottle that simultaneously forms a collection vessel.

Appellants respectfully submit that claim 1 is patentable for at least the reasons discussed below.

The Examiner alleges that Deverre discloses placental-blood extraction device, which includes an extraction needle and a collection bag. The Examiner concedes that Deverre fails to

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[19] In the Amendment filed December 1, 2009, claim 1 was amended to incorporate the subject matter of claim 11. This Amendment was entered by the Examiner in the Advisory Action dated December 9, 2009. Accordingly, the rejection of claim 11 is now applicable to claim 1.

[20] *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1391 (2007).

disclose a suction means as recited in claim 1. However, the Examiner alleges that Dracker discloses a suction means for sucking placental blood to feed a collection bag. Finally, the Examiner concedes that neither Deverre nor Dracker discloses a vacuum bottle that simultaneously forms the collection vessel. The Examiner alleges that Seddon discloses a Redon-type bottle, and that the proposed combination of Deverre, Dracker and Seddon would render claim 1 obvious.

A. Discussion of the References

Deverre discloses a placental blood collection line, which includes a rinsing bag. As shown in FIG. 1, Deverre discloses that a collection bag 1 is in fluid communication with collection needles 4 and 5 via a tube 2. Deverre also discloses that a rinsing bag 6 containing a rinsing solution is connected to the collection bag 1 through tube 7. According to Deverre, placental blood is collected using gravity (see col. 3, lines 56-57).

Dracker discloses a method and apparatus for storing umbilical blood. A flexible collection bag attached to a needle, wherein a vacuum pressure is applied to the flexible collection bag, further providing suction through the needle to facilitate removal of blood from the umbilical cord (col. 4, l. 45-53).

Seddon discloses a wound drainage system, using a Redon-type bottle (i.e., a vacuum type bottle). The Redon-type bottle includes a flask 1 which collects fluid and wound secretions by providing a low vacuum to a wound drainage tube 4.

B. There Is No Predictability That The Redon-Type Bottle Disclosed In Seddon Would Provide A Sufficient Vacuum For A Blood Collection Device, As Disclosed In Deverre And Dracker.

The Examiner must allow the claims, unless a person of ordinary skill can implement a predictable variation, in which case §103 likely bars its patentability.[21]

On page 3 of the Final Office Action mailed September 1, 2009, the Examiner acknowledges that Deverre fails to disclose suction means connected to at least one needle. The Examiner alleges that Dracker discloses a suction means, and that it would have been obvious to combine Deverre and Dracker. Further, the Examiner concedes that the proposed combination of Deverre and Dracker fails to disclose that "the suction means comprises a vacuum bottle that simultaneously forms a collection bottle," as recited in claim 1.[22] The Examiner alleges that Seddon discloses this feature, and argues that the proposed combination of Deverre, Dracker and Seddon renders claim 1 obvious.

Dracker discloses a flexible collection bag attached to the needle, wherein an outside vacuum source applies a vacuum to the flexible collection bag, further providing suction through the needle (col. 4, l. 45-53). In other words, the vacuum is applied from a separate device other than the flexible collection bag. Claim 1, on the other hand, recites that "said suction means comprises a vacuum bottle that simultaneously forms a collection vessel."

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[21] *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007).

[22] Final Office Action mailed September 1, 2009, at page 5.

As argued in the pre-appeal brief request for review submitted February 18, 2009, Appellants submit that it would not have been obvious for one of ordinary skill in the art to replace the active suction device (i.e., one that uses an applied vacuum) as disclosed in Dracker (or, alternatively, a simple syringe, which also requires an applied vacuum to create suction), with a Redon-type bottle, such as the passive device disclosed by Seddon, particularly given that Seddon relates to a wound drainage system and would, therefore, be incompatible for placental-blood extraction.

In the Response to Arguments, detailed on page 2 of the Final Office Action, the Examiner argues that Seddon is an active system, and disagrees that the vacuum bottles referenced in Seddon have no "accelerating" effect. Rather, the Examiner concludes that suction would necessarily result in quicker removal of a fluid when compared to a system that does not use suction, such as Deverre, which uses gravity.

Appellants respectfully submit that this conclusion is incorrect. The Examiner is not comparing a device with suction to a device without suction in the same application (e.g., blood collection). Thus, the Examiner's comparison of the device in Deverre with the device in Seddon is not on point.

In a blood collection device, blood flows much quicker out of the body than in a wound drainage system. Even without suction, as in the system disclosed in Deverre, blood flows rather quickly out of the veins (in particular due to pressure provided in the subject's body), and the blood collection is done in a short period of time (several minutes). According to wound drainage systems, as disclosed by the system disclosed in Seddon, however, the object is to

remove the fluids which appear at a wound site over several days. Without suction, these fluids would remain inside the wound, and the suction is only provided to remove these fluids from the wound. Collection of these fluids is not desired to be performed as quickly as possible, and in reality, the suction should be as low as possible. Thus, there is no indication or predictibility that a Redon-type bottle, as disclosed in Seddon, would be useful in a blood collection device, given that Redon-type bottles supply extremely low vacuums.[23]

C. The Low Vacuum Supplied By A Redon-Type Bottle Would Teach Away From Combination With The Blood Collection Devices Disclosed In Both Deverre And Dracker.

"A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.[24]

Appellants respectfully submit the use of a Redon-type (vacuum) bottle, as disclosed in Seddon, would teach away from the combination with blood collection systems as disclosed in Deverre and Dracker. The use of the vacuum bottle in a wound drainage system (slowly collecting fluids which otherwise would remain in the wound) is fundamentally different from the use of suction in a blood collection system (accelerating the blood collection to improve quantity and quality of the collected blood). Accordingly, one of ordinary skill in the art, trying

[23] *See* MPEP 2143.02(II), which indicates that a *prima facie* case of obviousness requires at least some degree of predictability, citing *In re Rinehart*, 531 F.2d 1048 (CCPA 1976). *See also,* MPEP 2143.01 (III), which indicates that simply because the references may be combined, the combination would not render the resulting combination obvious unless the results thereof would have been predictable, citing *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007).

[24] *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). *See* also, MPEP 2141.03(VI).

to improve a blood collection system, would not consider modifying the proposed combination of Deverre and Dracker using the Redon-type vacuum bottle, disclosed by Seddon, which relates to wound drainage.

Moreover, the disclosure in Dracker of a separate vacuum source teaches away from the use of a Redon-type bottle as a vacuum source in a blood collection application.

D. Combining Deverre And Seddon As Alleged By The Examiner Would Render The Vacuum Bottle Disclosed in Seddon Unfit For Its Intended Purpose.

"If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."[25]

Even if Deverre and Seddon were combined as alleged by the Examiner, Appellants submit that the resulting combination would not have resulted in the claimed subject matter, as the addition of the vacuum bottle disclosed in Seddon would not actually apply a vacuum to the system of Deverre. Specifically, Deverre uses a rinsing solution containing an anticoagulant and/or preservative to rinse the tubes of the collection device prior to blood collection. This anticoagulant/preservative is collected in the same collection bag as the umbilical cord blood. Accordingly, once the vacuum bottle would be opened, the bottle would fill with anticoagulant/preservative prior to the collection of the umbilical cord blood. The filling of the bottle with anticoagulant/preservative would eliminate the vacuum to be applied to the desired

[25] *In re Gordon*, 733 F.2d 900, (Fed. Cir. 1984). *See also* MPEP 2143.01(V).

umbilical cord blood. Thus, combining the vacuum bottle disclosed in Seddon with the system of Deverre would render the vacuum bottle disclosed in Seddon unsatisfactory for its intended purpose (i.e., applying a small vacuum for the slow collection of fluids), since the Examiner's proposed combination of Deverre and Seddon would not apply a suction for sucking the placental blood so as to feed said collection vessel.

E. Combining A Redon-Type Bottle With A Blood Collection System Has Strong Secondary Considerations For Patentability, As The Combination Has Never Been Proposed, Which Indicates That The Combination Of Elements Outlined In Claim 1 Is Inventive.

Evidence showing "secondary considerations" may show an indication of non-obviousness.[26] The failure of others to invent is relevant to the obviousness inquiry as such a secondary consideration.[27]

Redon bottles have been in use for wound drainage for many years. However, Redon-type bottles have never been used in connection with blood collection, and more specifically, with placental blood collection. Accordingly, Applicants submit that combining a Redon-type bottle with a blood collection systems has strong secondary considerations for patentability. Because the particular combination of well-known elements recited in claim 1 has never been proposed, this failure to propose the invention is a strong indication that the combination of elements outlined in claim 1 is inventive. Applicants note that several suction systems are

[26] *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

[27] *Ryko Manufacturing Co. v. Nu-star Inc.*, 950 F.2d 714 (Fed. Cir. 1991).

known which may be used for blood collection (e.g., a syringe or Dracker's flexible bag, submitted to vacuum), and each of these systems require a specific application of a vacuum to provide said suction. However, while the use of a Redon-type vacuum bottle is well known for wound drainage and collection, a Redon-type vacuum bottle has never been considered in connection with blood collection systems, due to its normal use of minimal vacuum to provide wound drainage slowly, over several days time.

Therefore, for the reasons set forth above, Appellants submit the Examiner's proposed combination of references would not render independent claim 1 obvious.

Independent claim 17 recites "wherein the collection vessel is of the Redon type." The prior art does not teach or suggest these combinations of features as explained above. Each of dependent claims, 2-7, 9, 12, and 19 are patentable at least by virtue of their respective dependencies from claims 1 and 17.

Claims 3 and 4 are patentable for reasons independent of their dependency.

Claim 3 recites, in part, "the device includes at least one injection or extraction site between said at least one extraction needle and said collection vessel." The Examiner alleges that Deverre discloses at least one injection/extraction site, citing elements 8 and 12 in FIG. 2. However, as noted at column 2, lines 41-43 and column 3, lines 5-7 of Deverre, elements 8 and 12 are merely couplings which couple tubes 2 and 7, or tube 2 and bag 11 together. These couplings are not provided with an opening which allows for injection or extraction, as recited in claim 3. Accordingly, claim 3 is patentable over the applied art.

Claim 4 recites, in part, "in which said at least one injection or extraction site is provided on the tube." As noted with regard to claim 3, Deverre fails to disclose at least one injection/extraction site located between the at least one extraction needle and said collection vessel. Therefore, Deverre also cannot disclose that the at least one injection/extraction location is provided on the tube. Accordingly, claim 4 is patentable over the applied art.

II. CLAIMS 13-16 STAND REJECTED UNDER 35 U.S.C. § 103(a) AS ALLEGEDLY BEING UNPATENTABLE OVER DRACKER IN VIEW OF SEDDON.

Independent claim 13 recites elements similar to independent claims 1 and 17. Therefore, for reasons analogous to those presented above with regard to independent claims 1 and 17, independent claim 13 is patentable over the applied art.

Claims 15 and 16 depend from claim 13 and are patentable at least by virtue of their dependency.

III. CLAIM 8 STANDS REJECTED UNDER 35 U.S.C. § 103(a) AS ALLEGEDLY BEING UNPATENTABLE OVER DEVERRE AND DRACKER AS APPLIED TO CLAIM 7 ABOVE, AND FURTHER IN VIEW OF DARLING, JR. (US PATENT 6,213,986).

Claim 8 depends from amended claim 1. Because the Examiner's proposed combination of Deverre and Dracker fails to render claim 1 obvious, and because Darling fails to cure the deficiencies noted with respect to amended claim 1, claim 8 is patentable at least by virtue of its dependency from amended claim 1.

IV. CLAIM 10 STANDS REJECTED UNDER 35 U.S.C. § 103(a) AS ALLEGEDLY BEING UNPATENTABLE OVER DEVERRE AND DRACKER AS APPLIED TO CLAIM 7 ABOVE, AND FURTHER IN VIEW OF VAN DER HEIDEN (US PATENT 5,879,318).

Claim 10 depends from amended claim 1. Because the Examiner's proposed combination of Deverre and Dracker fails to render claim 1 obvious, and because Van Der Heiden fails to cure the deficiencies noted with respect to amended claim 1, claim 10 is patentable at least by virtue of its dependency from amended claim 1.

V. CONCLUSION

For all of the above reasons, the Examiner's rejections are believed to be in error, and should be reversed.The USPTO is directed and authorized to charge the statutory fee (37 C.F.R. §41.37(a) and 1.17(c)) and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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Date: November 5, 2010

CLAIMS APPENDIX

CLAIMS 1-10, 12, 13, 15-17, 19 ON APPEAL:

1. A placental-blood extraction device comprising at least one extraction needle for piercing the vein of the umbilical cord or of the placenta, a collection vessel connected to said at least one needle via at least one tube, and suction means connected to said at least one needle for sucking the placental blood so as to feed said collection vessel;

wherein said suction means comprises a vacuum bottle that simultaneously forms a collection vessel.

2. A device according to claim 1, in which said suction means (further comprises a vacuum pump.

3. A device according to claim 1, in which the device includes at least one injection or extraction site between said at least one extraction needle and said collection vessel.

4. A device according to claim 3, in which said at least one injection or extraction site is provided on the tube.

5. A device according to claim 3, in which at least one injection or extraction site is provided on the collection vessel.

6. A device according to claim 3, in which said at least one injection or extraction site is used to inject an anti-coagulant and/or to extract a sample of blood for analysis and/or to extract the blood contained in said collection vessel.

7. A device according to claim 1, in which said device includes blood-flow control means or suction control means.

8. A device according to claim 7, in which said blood-flow control means or said suction control means include a knurled adjustment wheel.

9. A device according to claim 1, in which said collection vessel contains an anti-coagulant before receiving said placental blood.

10. A device according to claim 1, in which said device is packaged in sterile manner and is assembled in a single package so as to be ready to use once said package has been opened.

12. The device according to claim 1, wherein the vacuum bottle is of the Redon type.

13. A placental-blood extraction device comprising:

an extraction needle for piercing the vein of an umbilical cord or of a placenta,

a collection vessel in fluid connection with the needle via a tube, and

a vacuum in fluid connection with the needle so as to feed said collection vessel;

wherein the vessel creates the vacuum.

15. The device according to claim 13, wherein the vessel is of the Redon type.

16. The device according to claim 13, wherein a pump creates the vacuum.

17. A method of extracting fluid from an umbilical cord or a placenta comprising:

providing an extraction device comprising an extraction needle, a collection vessel in fluid connection with the needle via a tube, and a vacuum in fluid connection with the needle so as to feed said collection vessel; and

piercing the vein of the umbilical cord or of a placenta and drawing out fluid with the aid of the vacuum;

wherein the collection vessel is of the Redon type.

19. (previously presented) The method according to claim 17, further comprising the step of using a pump to aid in the extraction of the fluid.

EVIDENCE APPENDIX:

None.

RELATED PROCEEDINGS APPENDIX

None.